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UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE:	:	
Fosamax Products Liability Litigation	:	1:06-md-1789 (JFK)
	:	
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<i>This Document Relates to:</i>	:	<b>ANSWER AND ADDITIONAL</b>
Mary Guyant	:	<b>DEFENSES OF MERCK</b>
v. Merck & Co., Inc.	:	<b>&amp; CO., INC.;</b>
	:	<b>DEMAND FOR JURY TRIAL</b>
Case No: 1: 06-cv-10471-JFK	:	
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Defendant Merck & Co., Inc. ("Merck"), by its undersigned attorneys, hereby answers the Complaint and Demand for Jury Trial ("Complaint"). Merck denies all allegations set forth in the Complaint, except to the extent such allegations are specifically admitted below:

Merck denies each and every allegation of the introductory paragraph, except Merck admits that its principal place of business is located in Whitehouse Station, New Jersey and Merck states that it is without knowledge or information sufficient to form a belief as to the residence of Plaintiff.

**RESPONSE TO “GENERAL BACKGROUND AND OVERVIEW OF CLAIMS”**

1. Merck denies each and every allegation of Paragraph 1, except that Merck admits that Plaintiff purports to bring a civil action for damages, but denies that there is any factual or legal basis for same.

2. Merck denies each and every allegation of Paragraph 2, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 2 inconsistent with that prescribing information and respectfully refers the Court to the Physicians’ Desk Reference ("PDR") for FOSAMAX® for its actual language and full text.

3. Merck denies each and every allegation of Paragraph 3.

4. Merck denies each and every allegation of Paragraph 4.

5. Merck denies each and every allegation of Paragraph 5.

6. Merck denies each and every allegation of Paragraph 6.

7. Merck denies each and every allegation of Paragraph 7.

8. Merck denies each and every allegation of Paragraph 8.

9. Merck denies each and every allegation of Paragraph 9.

10. Merck denies each and every allegation of Paragraph 10, except that Merck admits that Plaintiff purports to bring a civil action for damages, but denies that there is any factual or legal basis for same.

**RESPONSE TO “JURISDICTION AND VENUE”**

11. The allegations contained in the first sentence of Paragraph 11 are legal conclusions as to which no responsive pleading is required. Should a response be

deemed required, Merck denies each and every allegation contained in the first sentence of Paragraph 11. As to the allegations of the second sentence of Paragraph 11, Merck admits that it is a corporation organized under the laws of the State of New Jersey with its principal place of business in New Jersey and states that it is without knowledge or information sufficient to form a belief as to Plaintiff's citizenship. As to the allegations contained in the third sentence of Paragraph 11, Merck states that it is without knowledge or information sufficient to form a belief as to the allegations of the third sentence of Paragraph 11 but, for jurisdictional purposes only, admits that the Plaintiff seeks in excess of \$75,000. The allegations contained in fourth sentence of Paragraph 11 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation of the fourth sentence of Paragraph 11, except that Merck states that it is without knowledge as to where Plaintiff resides or used FOSAMAX®.

12. The allegations contained in Paragraph 12 are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation of Paragraph 12.

13. The allegations of Paragraph 13 do not require a response. Should a response be deemed required, Merck denies each and every allegation of Paragraph 13, except states that it is without knowledge as to the residence of Plaintiff or her reasons for choosing the venue in which this case was filed.

#### **RESPONSE TO "PARTIES"**

14. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 14.

15. Merck admits the allegations of Paragraph 15.

16. Merck denies each and every allegation of Paragraph 16, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

17. Merck admits that it is authorized to do business in New York.

18. Merck is without knowledge as to what is meant by the phrase “regularly solicits and transacts business” so the allegations in Paragraph 18 are denied.

19. Merck denies each and every allegation of Paragraph 19, except that it admits that Merck manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 19 inconsistent with that prescribing information and respectfully refers the Court to the Physicians’ Desk Reference (“PDR”) for FOSAMAX® for its actual language and full text.

20. Merck is without knowledge as to what is meant by the phrase “substantial revenue” so the allegations in Paragraph 20 are denied.

21. Merck is without knowledge as to what is meant by “consequences,” so the allegations in Paragraph 21 are denied.

**RESPONSE TO “SUBSTANTIVE ALLEGATIONS”**

22. Merck denies each and every allegation of Paragraph 22, except that Merck admits that it sought and, in 1995, first obtained FDA approval to manufacture and market FOSAMAX® 10 mg and FOSAMAX® 40 mg tablets, a prescription medication approved by the FDA for prescription in accordance with its approved prescribing

information. Merck denies any allegations in Paragraph 22 inconsistent with that prescribing information.

23. Merck admits only that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information and denies any allegations in Paragraph 23 inconsistent with that prescribing information. Merck also refers the Court to the prescribing information for Aredia and Zometa, and denies any allegations in Paragraph 23 with respect to Aredia and Zometa inconsistent with that prescribing information.

24. Merck admits only that some bisphosphonates contain nitrogen and some do not and that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information. Merck denies any allegations in Paragraph 24 inconsistent with that prescribing information. Merck respectfully refers the Court to the PDR for FOSAMAX® for its actual language and full text. Merck also refers the Court to the prescribing information for Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid, and denies any allegations in Paragraph 24 with respect to Aredia, Bondronat, Didronel, Bonefos, Loron, and Skelid inconsistent with that prescribing information. Merck denies the remaining allegations of Paragraph 24.

25. Merck denies each and every allegation of Paragraph 25.

26. Merck denies each and every allegation of Paragraph 26.

27. Merck denies each and every allegation of Paragraph 27.

28. Merck denies each and every allegation of Paragraph 28.

29. Merck denies each and every allegation of Paragraph 29.

30. Merck denies each and every allegation of Paragraph 30.

31. Merck denies each and every allegation of Paragraph 31 except admits that the FDA has received reports of osteonecrosis of the jaw among users of Fosamax but avers that those reports are not necessarily accurate. Merck further denies that any of the reported cases of osteonecrosis of the jaw were caused by Fosamax. Merck avers that adverse events are reported without regard to causality and do not reflect a conclusion by a reporter that the event was caused by the drug.

32. Merck denies each and every allegation of Paragraph 32, except that Merck admits that the FDA drafted an "ODS Postmarketing Safety Review," but respectfully refers the Court to said document for its actual language and full text.

33. Merck denies each and every allegation of Paragraph 33.

34. Merck denies each and every allegation of Paragraph 34.

35. Merck denies each and every allegation of Paragraph 35.

36. Merck denies each and every allegation of Paragraph 36, except that Merck admits that Fosamax product sales in 2006 amounted to approximately \$3.13 billion.

37. Merck denies each and every allegation of Paragraph 37.

38. Merck denies each and every allegation of Paragraph 38.

39. Merck denies each and every allegation of Paragraph 39.

40. Merck is without knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in Paragraph 40.

41. Merck denies each and every allegation of Paragraph 41.

42. Merck denies each and every allegation of Paragraph 42, except that Merck admits that that Fosamax product sales in 2005 amounted to approximately \$3.19 billion.

**Response to “Plaintiff's Use of Fosamax”**

43. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 43.

44. Merck is without knowledge or information sufficient to form a belief as to the allegations of Paragraph 44.

45. Merck denies each and every allegation of Paragraph 45.

46. Merck denies each and every allegation of Paragraph 46.

47. Merck denies each and every allegation of Paragraph 47.

48. Merck denies each and every allegation of Paragraph 48.

**RESPONSE TO “EQUITABLE TOLLING OF APPLICATION  
STATUTES OF LIMITATIONS”**

49. Merck denies each and every allegation of Paragraph 49.

50. Merck denies each and every allegation of Paragraph 50.

51. Merck denies each and every allegation of Paragraph 51.

52. Merck denies each and every allegation of Paragraph 52.

**RESPONSE TO “FIRST CAUSE OF ACTION”  
Negligence”**

53. Merck repleads its answers to Paragraphs 1 through and including 52 and, by this reference, hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

54. The allegations in Paragraph 54 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

55. Merck denies each and every allegation of Paragraph 55.

56. Merck denies each and every allegation of Paragraph 56, including each and every allegation of subparagraphs (a) through (n).

57. Merck denies each and every allegation of Paragraph 57.

58. Merck denies each and every allegation of Paragraph 58.

59. Merck denies each and every allegation of Paragraph 59.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**RESPONSE TO "SECOND CAUSE OF ACTION"**  
**Strict Liability – Failure to Warn**

60. Merck repleads its answers to Paragraphs 1 through and including 59, and, by this reference, hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

61. Merck denies each and every allegation of the first sentence of Paragraph 61, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information. The allegations of the second sentence of Paragraph 61 are conclusions of law to which no response is required; to the extent that a response is



deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules.

62. Merck denies each and every allegation of Paragraph 62.

63. Merck denies each and every allegation of Paragraph 63.

64. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 64.

65. Merck denies each and every allegation of Paragraph 65.

66. Merck denies each and every allegation of Paragraph 66.

67. Merck denies each and every allegation of Paragraph 67.

68. Merck denies each and every allegation of Paragraph 68.

69. The allegations of the first sentence of Paragraph 69 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the relevant legal standard, including any conflict of law rules. Merck denies each and every allegation of the second sentence of Paragraph 69.

70. Merck denies each and every allegation of Paragraph 70.

71. Merck denies each and every allegation of Paragraph 71.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**RESPONSE TO “THIRD CAUSE OF ACTION”  
Strict Liability – Defective Design”**

72. Merck repleads its answers to Paragraphs 1 through and including 71, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

73. Merck denies each and every allegation of Paragraph 73, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

74. Merck denies each and every allegation of Paragraph 74, except that it admits that Merck manufactured, marketed and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information and states that it is without knowledge as to the condition of the FOSAMAX® Plaintiff alleges she consumed.

75. Merck denies each and every allegation of Paragraph 75.

76. Merck denies each and every allegation of Paragraph 76.

77. Merck denies each and every allegation of Paragraph 77.

78. Merck denies each and every allegation of Paragraph 78.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff’s Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**RESPONSE TO “FOURTH CAUSE OF ACTION”**  
**Breach of Express Warranty**

79. Merck repleads its answers to Paragraphs 1 through and including 78, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

80. Merck denies each and every allegation of Paragraph 80, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

81. Merck denies each and every allegation of Paragraph 81.

82. Merck denies each and every allegation of Paragraph 82.

83. Merck denies each and every allegation of Paragraph 83.

84. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 84.

85. Merck denies each and every allegation of Paragraph 85.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff’s Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**RESPONSE TO “FIFTH CAUSE OF ACTION”  
Breach of Implied Warranty”**

86. Merck repleads its answers to Paragraphs 1 through and including 85, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

87. Merck denies each and every allegation of Paragraph 87, except that Merck admits that it manufactured, marketed, and distributed the prescription medicine FOSAMAX® for prescription in accordance with its approved prescribing information.

88. Merck denies each and every allegation of Paragraph 88, and respectfully refers the Court to the FDA-approved prescribing information for any and all representations contained therein. Merck further avers that FOSAMAX® is a prescription medication approved by the FDA for prescription in accordance with its approved prescribing information.

89. Merck denies each and every allegation of Paragraph 89.

90. Merck denies each and every allegation of Paragraph 90.

91. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 91.

92. Merck lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of Paragraph 92.

93. Merck denies each and every allegation of Paragraph 93.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff’s Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**RESPONSE TO “SIXTH CAUSE OF ACTION  
Common Law Fraud”**

94. Merck repleads its answers to Paragraphs 1 through and including 93, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

95. Merck denies each and every allegation of Paragraph 95.

96. Merck denies each and every allegation of Paragraph 96.

97. Merck denies each and every allegation of Paragraph 97.

98. Merck denies each and every allegation of Paragraph 98.

99. Merck denies each and every allegation of Paragraph 99.

100. Merck denies each and every allegation of Paragraph 100.

101. Merck denies each and every allegation of Paragraph 101.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**RESPONSE TO “SEVENTH CAUSE OF ACTION  
Fraudulent Concealment”**

102. Merck repleads its answers to Paragraphs 1 through and including 101, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

103. Merck denies each and every allegation of Paragraph 103, including each and every allegation of subparts (a) and (b).

**RESPONSE TO “EIGHTH CAUSE OF ACTION  
Punitive Damages”**

104. Merck repleads its answers to Paragraphs 1 through and including 103, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

105. Merck denies each and every allegation of Paragraph 105.

106. Merck denies each and every allegation of Paragraph 106.

107. Merck denies each and every allegation of Paragraph 107.

108. Merck denies each and every allegation of Paragraph 108.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**RESPONSE TO “NINTH CAUSE OF ACTION  
Negligence Per Se”**

109. Merck repleads its answers to Paragraphs 1 through and including 108, and by this reference hereby incorporates the same herein in this paragraph, and makes the same a part hereof as though fully set forth *verbatim*.

110. Merck admits the allegations of Paragraph 110.

111. Merck denies each and every allegation of Paragraph 111.

112. The allegations in Paragraph 112 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the referenced section of the United States Code for its actual language and full text.

113. The allegations in Paragraph 113 are conclusions of law to which no response is required; to the extent that a response is deemed necessary, the allegations are denied and Merck respectfully refers the Court to the referenced section of the United States Code for its actual language and full text.

114. Merck denies each and every allegation of Paragraph 114.

115. Merck denies each and every allegation of Paragraph 115.

#### **PRAYER FOR RELIEF**

Merck denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiffs' Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

#### **DEFENSES**

Discovery and investigation may reveal that any one or more of the following defenses should be available to Merck in this matter. Merck, therefore, asserts said defenses in order to preserve the right to assert them. Upon completion of discovery, and if the facts warrant, Merck may withdraw any of these additional defenses as may be appropriate. Further, Merck reserves the right to amend its Answer to assert additional defenses, cross-claims, counterclaims, and other claims and defenses as discovery proceeds. Further answering and by way of additional defense, Merck states as follows:

#### **FIRST DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the applicable statute of limitations and is otherwise untimely.

**SECOND DEFENSE**

The Complaint fails to state a claim upon which relief can be granted.

**THIRD DEFENSE**

Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**FOURTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**FIFTH DEFENSE**

To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**SIXTH DEFENSE**

To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of FOSAMAX®, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warnings to the prescribing physician.

**SEVENTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were caused in whole or in part by the contributory negligence of the allegedly injured Plaintiff.



**EIGHTH DEFENSE**

Any liability that might otherwise be imposed upon this Defendant is subject to reduction by the application of the doctrine of comparative fault codified at Ind. Code § 34-51-2-1 *et. seq.*

**NINTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses were only sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any medicine or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**TENTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**ELEVENTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of FOSAMAX®.

**TWELFTH DEFENSE**

If Plaintiff has sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases, or illnesses, idiosyncratic reactions,

subsequent medical conditions or natural courses of conditions for which this Defendant is not responsible.

**THIRTEENTH DEFENSE**

To the extent that Plaintiff relies upon any theory of breach of warranty, such claims are also barred for lack of timely notice of breach and/or lack of privity and/or the alleged warranties were disclaimed.

**FOURTEENTH DEFENSE**

Plaintiff's claims are barred in whole or in part because FOSAMAX® was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**FIFTEENTH DEFENSE**

Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**SIXTEENTH DEFENSE**

To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused the injuries asserted in the Complaint, such an award would, if granted, violate Merck's state and federal constitutional rights.

**SEVENTEENTH DEFENSE**

To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless or grossly negligent and, therefore, any award of punitive damages is barred. The acts of Merck were at all times done in good faith and without malice.

**EIGHTEEN DEFENSE**

Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**NINETEEN DEFENSE**

Plaintiff's claims are barred in whole or in part because Merck provided legally adequate "directions or warnings" as to the use of FOSAMAX® and any other medicine or pharmaceutical preparation Plaintiff alleges to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**TWENTIETH DEFENSE**

Plaintiff's claims are barred under Section 4, *et seq.*, of the Restatement (Third) of Torts: Products Liability.

**TWENTY-FIRST DEFENSE**

With respect to each and every cause of action, Plaintiff is not entitled to recover because if the product involved was unsafe, which Merck denies, then it was unavoidably unsafe as defined in Restatement of Torts. The apparent benefits of the product exceeded any apparent risk given the scientific knowledge available when the product was marketed..

**TWENTY-SECOND DEFENSE**

There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of FOSAMAX®.

**TWENTY-THIRD DEFENSE**

Plaintiff's claims are barred in whole or in part by failure to mitigate or prevent the damages claimed.

**TWENTY-FOURTH DEFENSE**

Merck's advertisements and labeling with respect to the products which are the subject matter of this action were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States and Indiana Constitutions.

**TWENTY-FIFTH DEFENSE**

At all times relevant herein, any product which is the subject matter of this action manufactured and distributed by Merck in any state in the United States was manufactured and distributed in a reasonable and prudent manner based upon available medical and scientific knowledge and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

**TWENTY-SIXTH DEFENSE**

To the extent there were any risks associated with the use of the product which is the subject matter of this action which Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and state law.

**TWENTY-SEVENTH DEFENSE**

Plaintiff has not sustained an ascertainable loss of property or money.

**TWENTY-EIGHTH DEFENSE**

Plaintiff has not suffered any actual injury or damages.

**TWENTY-NINTH DEFENSE**

This case is more appropriately brought in a different venue as defined in 28 U.S.C. §1404(a).

**THIRTIETH DEFENSE**

This case is subject to dismissal and/or transfer to another venue pursuant to 28 U.S.C. §1406(a).

**THIRTY-FIRST DEFENSE**

This case is subject to dismissal or stay on the grounds of *forum non conveniens*.

**THIRTY-SECOND DEFENSE**

Plaintiff's claims of fraud are not pleaded with the required particularity, pursuant to Federal Rule of Civil Procedure 9(b)

**THIRTY-THIRD DEFENSE**

Plaintiff cannot recover for the claims asserted because Plaintiff has failed to comply with the conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiff.

**THIRTY-FOURTH DEFENSE**

Plaintiff's claims for breach of warranty are barred because Plaintiff did not rely on such warranties and the claims are otherwise barred for lack of timely notice, lack of privity and/or because the alleged warranties were disclaimed.

**THIRTY-FIFTH DEFENSE**

Merck is entitled to a set-off or reduction in any damages which may be awarded to the Plaintiff for any amounts received from collateral sources.

**THIRTY-SIXTH DEFENSE**

An asymptomatic plaintiff lacks standing because she has suffered no damages and no injury-in-fact.

**TWENTY-SEVENTH DEFENSE**

Plaintiff's claimed are barred under the doctrine of economic loss

**THIRTY-EIGHTH DEFENSE**

To the extent that Plaintiffs assert claims based on Merck's adherence to and compliance with applicable state laws, regulations and rules, such claims are preempted by federal law under the Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biologic Products, FDA Docket No. 2000N-1269 (January 24, 2006).

**THIRTY-NINTH DEFENSE**

To the extent that Plaintiffs seek punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, be subject to the limitations of Ind. Code § 34-51-3-1 *et seq.*

**FORTIETH DEFENSE**

Merck reserves its right to assert a "non-party defense" under Indiana law.

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In so much as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and/or supplement the averments of its Answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck such other and further relief that the Court may deem just and proper.

**JURY DEMAND**

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York  
December 10, 2007

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: \_\_\_\_\_/s/  
Norman C. Kleinberg  
Theodore V. H. Mayer  
William J. Beausoleil

One Battery Park Plaza  
New York, New York 10004-1482  
(212) 837-6000

*Attorneys for Defendant Merck & Co., Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on this 10<sup>th</sup> day of December, 2007, I caused a copy of the foregoing ANSWER AND AFFIRMATIVE DEFENSES OF MERCK & CO., INC. to be served via first-class mail, postage prepaid, on the following:

HOVDE, DASSOW & DEETS, LLC  
Robert T. Dassow  
10585 N. Meridian Street, Suite 205  
Indianapolis, IN 46290

The above addresses have appeared on the prior papers in this action as the office address of the attorneys for Plaintiff.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on December 10, 2007

/s/  
Sarah A. Binder